REMARKS

I. Rejection under 35 U.S.C. 112, first paragraph.

Claims 29-33, 37, 38 and 53 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. According to the Examiner, the pending claims encompass a large genus of nucleic acids for which Applicants have only provided four particular nucleic acids and that at least 40^4 (about 2.5 million) different possibilities exist, out of which Applicants have described four (i.e. 1872 and 1874-1876).

Applicants respectfully disagree that the specification fails to provide a written description for the claimed genus. The specification clearly describes the claimed genus, specifically nucleic acid molecules encoding a protein having SEQ ID NO::1873 or a protein that has 95% identity with SEQ ID NO: 1873 and chloride channel activity. Based on the Examiner's arguments, as presented in the paragraph bridging pages 4 and 5 and on pages 6-7 of the Final Office Action, the Examiner appears to recognize the 95% identity as the only limitation to the genus, while failing to recognize the chloride channel activity as a limitation. According to the Examiner, "this [chloride channel activity] is not either a functional or structural limitation" and cites Jentsch et al. as support. Applicants, however, submit that Jentsch et al., in fact, supports Applicants' position that the chloride channel activity should be a recognized functional limitation. As acknowledged by the Examiner on page 7 of the Final Office Action (first full paragraph), Jentsch et al. note that the "ultimate **function is similar (providing a pathway for the passive diffusion of anions)**, this diversity in function could most easily be achieved by the evolution of many distinct Cl channels (encoded by different genes)." Thus, the term chloride channel activity does have a definite function (i.e., a pathway for the passive diffusion of chloride anions) as recognized by Jentsch et al.

Here, Applicants submit it is irrelevant that different chloride ion channels can have different physiological tasks and are encoded by different nucleic acid molecules because Applicants are not claiming all such nucleic acid molecules. Rather, Applicants are only claiming a specific subset of such nucleic acid molecules, namely those that have the amino acid sequence of SEQ ID NO: 1873 or 95% identical to the sequence of SEQ ID NO: 1873 coupled with the ability to provide the passive diffusion of chloride ions. Such passive diffusion of chloride channel activity can be readily determined by one skilled in the art. Thus, Applicants are not attempting to claim all 40^4 possibilities as asserted by the Examiner, but only those that also have chloride channel activity.

Without the details of the USPTO's sequence search, Applicants cannot comment on the USPTO's inability to confirm that SEQ ID NO:1872 has 37.5% identity with Accession No. NM001289 (Homo sapiens chloride intracellular channel 2). In accordance with the teachings of the specification, the percent identities were determined by using the GCG Wisconsin Package Version 9.0 sequence analysis software (see page 112, lines 7-8 and page 203, lines 1-2).

Regarding the nucleic acid sequence alignments for laminin (Accession No. AB725018/c) and human ion channel (Accession No. AAD27280) provided by the Examiner, Applicants note again that the alignments do not provide any "reason to doubt" that the claimed nucleic acid molecules encode chloride channels because those aligaments are to reverse strands relative to the nucleic acid molecules of the present invention and therefore probably do not even encode proteins, much less a protein that would cast doubt upon the identity of proteins of the present invention. One of skill in the art would recognize that protein sequence alignments, such as those provided by the Applicants in the First Response, are much more persuasive indicators of a protein's identity.

In addition, it is interesting to note that according to the Examiner, SEQ.ID.NO:1873 shares 52.5% identity over the same 236 bp (443-678) to "two entirely different classes of proteins." Given this percent identity over the same region among entirely different classes of proteins, one skilled in the art could reasonably conclude that region does not impart the different activities for which such proteins are known. Therefore, it is reasonable to conclude that the chloride channel activity falls within a different region.

As urged in the response dated May 21, 2004 ("First Response"), Applicants have also attempted to follow the model as set forth in Training Example No. 14 of the Synopsis of Application of Written Description Guidelines, which was prepared by the USPTO to train Examiners how to apply the requirements set out in Federal Register, Vol. 66, No. 4, pages 1099-1111. Briefly, Example 14 claims a protein having SEQ ID NO:3 and variants that are at least 95% identical to SEQ ID NO:3 and catalyze the reaction of A to B, which is similar to the language of pending Claim 29.

Applicants again note that the USPTO analysis correctly concludes that description of the necessary common attributes of the genus is what is required to satisfy 35 U.S.C. 112, first paragraph, and not physical possession of some arbitrary number of species exhibiting that activity. Accordingly, Applicants respectfully assert, and argue that the USPTO analysis concurs, that a single disclosed species can adequately define a genus of structurally similar molecules having the same functional property, and is thus consistent with the requirements as set forth in *Lilly* 119 F3d at 1569, 43 USPQ2d at 1406, which calls for "recitation of a representative number of polypeptide sequences *** **or of a recitation of structural features common to the genus**" (emphasis added). Here, the structural features common to the genus is that a nucleic acid molecule falling within the claims must encode a protein at least 95%

identical in sequence to SEQ.ID.NO:1873. This situation is analogous to Example 14 of the guidelines and, therefore, should be treated similarly.

Applicants contention that *Fiers v. Revel* 25 USPQ2d 1601 ("*Fiers*") does not support the present rejection as presented in the First Response was not commented upon in the Final Office Action. In the First Response, Applicants contended that similar to the Sugano application, the instant specification contains a disclosure of a complete and correct sequence. Accordingly, Applicants submit that the court's discussion of the Sugano application, and therefore the ultimate ruling of *Fiers*, supports the Applicants' argument that the instant claims are adequately supported. In fact, once interference proceedings were concluded and Sugano was allowed to prosecute his case, the written description contained therein was found sufficient to support claims covering nucleic acid molecules other than the sequences specifically disclosed (See claim 1 of U.S. Patent No 5,326,859, which reads "A DNA which consists essentially of a DNA which codes for human fibroblast B_1 interferon polypeptide"). The claim allowed in the Sugano application is conceivably broader than a claim that has a 95% identity limitation.

With regard to the Examiner's concern that the claims encompass alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants, but the specification fails to provide a written description for them, Applicants contend ample written description has been provided in the specification for allelic variants, alternative splicing, and additional upstream and downstream sequences of nucleic acid molecules encoding proteins having 95% identity with SEQ ID NO: 1873. For example, on page 65, lines 7-18, on page 120, lines 11 and 20, and on page 122, lines 17 and 20, the specification contains a detailed discussion about allelic variants and alternative splicing. The specification also explicitly discloses nucleic acid molecules operatively linked to expression vectors, which can contain regulatory sequences,

signal sequences and fusion sequences, for example, on pages 127-129. From the written description, Applicants submit one skilled in the art can readily identify what is encompassed by the limitation having "at least 95% identical to SEQ.ID.NO: 1873." Applicants accordingly submit the specification provides ample written description.

Accordingly, In view of the foregoing, Applicants respectfully request withdrawal of the Examiner's rejection of Claims 29-33, 37, 38 and 53 under 35 U.S.C. 112, first paragraph.

II. Rejection Under 35 U.S.C. 112, Second Paragraph

Claims 48-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants have amended Claims 48-52 to clarify that only two types of nucleic acid molecules are in the claim. Claim 53 has not been amended since it relates back to Claim 29 and not Claim 48.

III. Rejection Under 35 U.S.C. 101

Claims 29-33, 37, 38 and 48-53 stand rejected under 35 U.S.C. 101 for lack of patentable utility. Although the Examiner acknowledges the claims have a credible utility, the claims allegedly fail to provide a well established utility or substantial utilities disclosed in the specification.

Applicants maintain their traversal of the Examiner's rejection and contend that the present specification sets forth patentable utility as set forth in the guidance provided by the USPTO's Revised Interim Utility Guidelines Training Materials, and in particular, Example 10. As asserted in the previous response dated May 21, 2004 ("First Response"), according to Example 10 of the guidelines, when a claimed sequence shows significant homology to a known

family of proteins, and the next most homologous protein outside the family has a significantly lower homology and an unrelated function, then there is "no reason to doubt" the claimed protein has the function of the proteins in the family. Applicants attached protein alignments in the First Response showing that the highest 40 hits representing characterized proteins are chloride channel proteins. Accordingly, Applicants contend that given the stated identities and availability of data regarding highly related families of proteins, one of skill in the art would place the protein encoded by the claimed nucleic acid molecule in the chloride channel family.

According to the Examiner, Jentsch et al. reports that there are potentially hundreds of different chloride channels, performing a lot of different functions in different cells and with different structures. However, as acknowledged by the Examiner on page 7 of the Final Office Action (first full paragraph), Jentsch et al. note that the "ultimate function is similar **(providing a pathway for the passive diffusion of anions)**." Thus, the term chloride channel activity does have a definite function (i.e., a pathway for the passive diffusion of chloride anions) as recognized by Jentsch et al.

Again, Applicants submit it is irrelevant that different chloride ion channels can have different physiological tasks as reported by Jentsch et al. since Applicants are not claiming all nucleic acid molecules that encode a protein having chloride channel activity. Rather, Applicants are only claiming a specific subset of such nucleic acid molecules, namely those that have the amino acid sequence of SEQ ID NO: 1873 or 95% identical to the sequence of SEQ ID NO: 1873 coupled with the ability to provide the passive diffusion of chloride ions.

The Examiner then contends that the claims are not supported by a specific utility because the disclosed uses of the nucleic acids are not specific and are generally applicable to any nucleic acid, namely to detect other nucleic acid molecules, preparation of oligonucleotides

for probes, primers or antisense molecules, preparation of recombinant vectors, and vaccines. According to the Examiner, these uses are non-specific and are not particular to the nucleic acids being claimed.

Applicants respectfully disagree with the Examiner's position that the specification fails to provide uses that are specific for the claimed molecules. Ample specific uses are disclosed throughout the specification. For example, on pages 137-138 and pages 143-144, the disclosure teaches that therapeutic compositions, such as isolated flea HMT and/or HNC nucleic acid molecules, when administered to an animal is capable of protecting or treating flea infestation. This specific use is not generally applicable to all nucleic acid molecules.

CONCLUSION

For the foregoing reasons, Applicants request the withdrawal of the rejection under 35 U.S.C. 101 and 35 U.S.C. 112 and solicit an allowance of the claims.

In the event the Examiner has any questions regarding this application, the Examiner is invited to contact the Applicants' undersigned representative.

Respectfully submitted,

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